US-PAT-NO: 5868779

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TITLE: Apparatus and methods for dilating vessels and hollow-body organs

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Abstract Text - ABTX (1):

Apparatus and methods for dilating a vessel or organ, especially a larger diameter vessel or organ, are provided using a catheter having a **balloon** element is disposed within a sheath having an **expandable** but **non-compliant mesh** region covering the **balloon** element. The sheath is selected from among a plurality of sheaths each having a **mesh** member that is **expandable** to a different predetermined **expanded** diameter, the **mesh** region preventing the **balloon** member from developing bulges during inflation and constraining the edges of the **balloon** from perforating the vessel in the event of perforation. The sheath, which extends to a proximal end of the catheter, is also employed to reduce the diameter of the balloon member following the dilatation procedure, thereby preventing the balloon from bunching up in the vessel or organ.

Brief Summary Text - BSTX (7):

Balloon dilatation devices generally employ either minimally-compliant balloons, which experience a relatively small increase in diameter when the balloon is expanded, or compliant balloons, which experience a relatively large

increase in diameter in response to an increase in pressure, as described, for example, in U.S. Pat. No. 5,447,497 to Sogard et al. **Non-compliant balloons** are generally favored for angioplasty because they may be reliably **expanded** to a known size, whereas compliant **balloons** permit treatment over a larger range of diameters. In order to provide a mixture of the desirable characteristics of each of these types of balloons, dilatation devices have been designed, as described in U.S. Pat. No. 5,447,497, that include layers of both compliant and non-compliant material.

Brief Summary Text - BSTX (8):

Other **balloon** dilatation devices have employed elastomer impregnated **braided** material or **nets** to constrain the inflated size of the device, such as described in U.S. Pat. No. 4,702,252 to Brooks et al. and U.S. Pat. No. 4,108,236 to Ochiai et al. Still other devices, such as described in U.S. Pat. No. 4,998,539 to Delsanti and U.S. Pat. No. 5,221,261 to Termin et al. include members for supporting a vessel following angioplasty. U.S. Pat. No. 4,998,539 describes a separately movable plaited **net** disposed over a **balloon** catheter. The plaited **net is expanded** against the interior of the vessel by the **balloon** during angioplasty, and temporarily remains in place after **balloon** deflation to prevent detachment of material from the vessel wall.

Brief Summary Text - BSTX (20):

In one preferred embodiment of the apparatus of the present invention, a catheter having a **balloon** element is disposed within a sheath having an **expandable** but **non-compliant mesh** region covering the **balloon** element. In

accordance with the present invention, the sheath is selected from among a plurality of sheaths each having a **mesh** member that is **expandable** to a different predetermined diameter. The **expandable mesh** region prevents the **balloon** member from developing bulges during inflation, and constrains the edges of the **balloon** from dissecting or rupturing the vessel in the event of **balloon** rupture. The sheath, which extends to a proximal end of the catheter, is also employed to reduce the diameter of the balloon member following the dilatation procedure, thereby preventing the balloon from bunching up in the vessel or organ.

Brief Summary Text - BSTX (21):

In alternative embodiments, a plurality of sheaths having **mesh** regions of different predetermined **expanded** diameters may be provided as separate elements designed to be used in conjunction with any previously known **balloon** catheters, so that a previously known catheter may be modified for use in treating hardened stenoses or larger diameter vessels. Methods of using the apparatus of the present invention to dilate vessels and organs are also provided.

Detailed Description Text - DETX (3):

Referring to FIG. 1, illustrative apparatus 10 constructed in accordance with the present invention is described. Apparatus 10 includes catheter 11 having **balloon** element 12 and sheath 13 having **expandable** but **non-compliant** **mesh** 14 disposed over **balloon** element 12. In accordance with the present invention, apparatus 10 may be provided wherein the **non-compliant mesh** may be selected from among a plurality, in which each **non-compliant mesh** has a

different predetermined **expanded** diameter.

Detailed Description Text - DETX (5):
Referring to FIG. 3, sheath 13 is joined in distal end region 30 to **expandable mesh** 14. **Expandable mesh** 14 includes rigid retainer ring 15 disposed from the distal end of **expandable mesh** 14 that engages distal end 16 of catheter 11. Rigid retainer ring 15 maintains **expandable mesh** 14 aligned with **balloon** member 12, and prevents proximal force on retractor knob 23 from pulling the **expandable mesh** to a position proximal to **balloon** element 12. Sheath 13 is shorter than catheter 11 so that, when sheath 13 is disposed over catheter 11, retraction of retractor knob 23 in the proximal direction will not interfere with inflation port 22.

Detailed Description Text - DETX (6):
As shown in FIG. 4, **expandable mesh** 14 contacts the exterior surface of **balloon** element 12. **Expandable mesh** 14 comprises a very low compliance material, such as a monofilament polyester **mesh, or a mesh** formed of stainless steel, Kevlar.RTM. (a fiber produced from poly-paraphenylene terephthalamide, sold by E. I. DuPont de Nemours, Wilmington, Del.), nickel-titanium alloy or other high strength material, so that the maximum inflated size of the device is determined by the predetermined **expanded** diameter of **mesh** 14. The filaments of **expandable mesh** 14 move with respect to one another so that upon inflation of the **balloon** element, the **mesh** 14 **expands** and pulls sheath 13 and retractor ring 23 in the distal direction. After **balloon** element 12 is deflated, **expandable mesh** 14 may be returned to its contracted state by pulling proximally on retractor ring 23.

Detailed Description Text - DETX (7):

It is contemplated that use of sheath 13 and **expandable mesh** 14, in conjunction with previously known **balloon** catheters, will enable the **balloons** of those devices to be inflated to twice or more the rated burst pressures, without rupture. For example, applicant has determined that a balloon having a rated pressure of 5 atmosphere may be safely inflated to about 25-30 atm without rupture. In addition, by selection of a desired predetermined **expanded** diameter of **mesh** 14, it is expected that **balloons** of previously known catheters may be inflated to diameters twice or more larger than the rated diameters of those **balloons** when used with the sheath and **expandable mesh** of the present invention, again without rupture.

Detailed Description Text - DETX (8):

It is further contemplated that **expandable mesh** 14 of the present invention imposes a radial and longitudinal stress on the **balloon** element during inflation that tends to equalize the circumferential and longitudinal stresses developed in the **balloon** member. This equalization of stresses around the balloon element is expected to reduce the risk of bulging and concomitant localized loss of strength of the balloon element. Moreover, **expandable mesh** 14 serves to confine the edges of **balloon** element 12 in those few cases where the **balloon** does rupture, thereby reducing the risk of dissection of a vessel caused by rupture, and trapping any pieces of the perforated **balloon** element.

Detailed Description Text - DETX (9):

In a preferred embodiment of the present invention,

catheter 11 and balloon element 12 may comprise materials commonly used in previously known balloon catheters, e.g., polyethylene or PET. Balloon element 12 may also comprise a compliant material, such as nylon. Sheath 13 preferably comprises a material commonly used in catheter construction, such as polyethylene or polyvinylchloride, while **expandable mesh** 14 preferably comprises a structure woven from polyethylene strands (i.e., monofilament polyester **mesh**). Alternatively, **expandable mesh** 14 may comprises strands of another polymer, Kevlar.RTM., stainless steel, nickel-titanium alloy or other high strength material. Preferably, the cross-points of the **mesh** are not interconnected, so that the strands may slide freely over one another when **balloon** element 12 is inflated. Sheath 13 and retainer ring 15 may be joined to **expandable mesh** 14 using any suitable method, such as thermowelding or biocompatible adhesive.

Detailed Description Text - DETX (10):

Operation of apparatus 10 of the present invention is now described for dilating a vessel. Typically, guidewire 40 first is disposed across a stenosis using an introducer catheter, as is well known in the art. Retractor knob 23 of sheath 13 is pulled in the proximal direction to elongate **expandable mesh** 14, and apparatus 10 is then advanced along guidewire 40 so that **balloon** element 12 is disposed across the stenotic region under fluoroscopic guidance, as determined, for example, using radio-opaque markers contained within **balloon** element 12.

Detailed Description Text - DETX (11):

Balloon element 12 is then inflated via lumen 24 and

inflation port 22. In accordance with the methods of the present invention, **balloon** element 12 is inflated to until constrained by **expandable mesh** 14, which in turn will **expand** only to its predetermined **expanded** diameter, and no further. Balloon element 12 may be expanded to twice or more its rated pressure, or twice or more its rated diameter, without bulging or rupture. As **balloon** element 12 **expands,** **expandable mesh** 14 opens to its predetermined **expanded** diameter, thereby causing disruption of the stenosis (e.g., compressing or cracking plaque to restore the patency of the vessel or organ).

Detailed Description Text - DETX (12):

Upon completion of the step of dilating the vessel, as determined, for example, by angiography, balloon element 12 is deflated. The clinician then grasps retractor knob 23, and while holding catheter 11 steady using luer 21, pulls retractor knob 23 in the distal direction, thereby contracting **expandable mesh** 14 to approximately its initial diameter. Apparatus 10 may then be withdrawn proximally from the patient's vessel or organ.

Detailed Description Text - DETX (13):

With respect to FIG. 5, apparatus 50 constructed in accordance with the present invention is described. Apparatus 50 comprises sheath 51, **expandable mesh** 52, retainer ring 53 and retractor knob 54. Apparatus 50 is constructed as described hereinabove with respect to the similar components of apparatus 10 of FIG. 1, and is intended to be used with commercially available, previously known, balloon catheters. In particular, apparatus 50 is intended to be slipped onto a previously known catheter to provide the same benefits as

apparatus 10 of FIG. 1. Retainer ring 53 is sized so that it engages the
distal neck of the **balloon** element, and thus cannot be pulled too far in the
proximal direction (i.e., retainer ring 53 keeps **expandable mesh** 52 aligned
with and disposed over the **balloon** element).

Detailed Description Text - DETX (15):
Apparatus 60 includes sheath 63 having **expandable mesh** 64 and retainer ring
65. In accordance with this aspect of the invention, sheath 63 includes an
elongate aperture or slit 66 through which guidewire 75 exits sheath 63. In
this manner, sheath 63 is free to move distally (upon inflation of balloon
element 63) or proximally (when pulled by retractor knob 67), without
interfering with guidewire 75.

Claims Text - CLTX (5):
a **mesh** portion attached to the distal end of the sheath and disposed
surrounding the **balloon** for sliding movement relative thereto, the **mesh** portion
comprising a **non-compliant** material having a first state wherein the **mesh**
portion has a first length and an insertion diameter and a second state wherein
the **mesh** portion has second length, shorter than the first length, and a
selected predetermined **expanded** diameter; and

Claims Text - CLTX (7):
wherein, when the **balloon** is fully inflated, the **mesh** portion is in the
second state and attains the selected predetermined **expanded** diameter, the **mesh**
portion constraining the **balloon** from further expansion.

Claims Text - CLTX (8):
2. The apparatus as defined in claim 1 wherein the **mesh**

portion enables the
balloon to be expanded to at least twice a rated burst pressure of the **balloon**.

Claims Text - CLTX (9):
3. The apparatus as defined in claim 1 wherein the **mesh** portion enables the
balloon to be inflated to at least twice a rated inflation pressure of the
balloon.

Claims Text - CLTX (11):
a retainer ring disposed on the distal end of the **mesh** portion, the retainer
ring engaging the catheter at a position distal of a distal neck of the
balloon.

Claims Text - CLTX (17):
a sheath selected from among a plurality of sheaths, each one of the
plurality of sheaths including a **mesh** portion having a predetermined **expanded**
diameter, each one of the sheaths comprising:

Claims Text - CLTX (19):
a **mesh** portion attached to the distal end of the tubular member and disposed
surrounding the **balloon** for sliding movement relative thereto, the **mesh** portion
comprising a **non-compliant** material having a first state wherein the **mesh**
portion has a first length and an insertion diameter and a second state wherein
the **mesh** portion has second length, shorter than the first length, and a
predetermined **expanded** diameter; and

Claims Text - CLTX (21):
wherein, when the **balloon** is fully inflated, the **mesh** portion of the
selected one of the plurality of sheaths is in the second

state and attains the
predetermined **expanded** diameter, the **mesh** portion
constraining the **balloon** from
further expansion.

Claims Text - CLTX (22):
9. The kit as defined in claim 8 wherein the **mesh**
portion of at least one
of the plurality of sheaths enables the **balloon to be expanded** to at least
twice a rated diameter of the **balloon**.

Claims Text - CLTX (23):
10. The apparatus as defined in claim 8 wherein the **mesh** portion of at
least one of the plurality of sheaths enables the **balloon**
to be inflated to at
least twice a rated inflation pressure of the **balloon**.

Claims Text - CLTX (25):
a retainer ring disposed on the distal end of the **mesh**
portion, the retainer
ring engaging the shaft at a position distal of a distal
neck of the **balloon**.

Claims Text - CLTX (30):
providing apparatus comprising a catheter a distal end
and a **balloon**
disposed on the distal end and a sheath disposed on the
catheter, the sheath
including a **mesh** portion aligned with and surrounding the **balloon, the mesh**
portion arranged for sliding movement relative to the **balloon, the mesh** portion
comprising a **non-compliant** material having a first state
wherein the **mesh**
portion has a first length and an insertion diameter and a
second state wherein
the **mesh** portion has second length, shorter than the first
length, and a
selected predetermined **expanded** diameter;

Claims Text - CLTX (33):
advancing the apparatus along the guidewire to position the **mesh** portion and
balloon within the constriction; and

Claims Text - CLTX (34):
inflating the **balloon** so that the **mesh** portion **expands** to the second state
and attains the selected predetermined diameter to disrupt the constriction,
the **mesh** portion constraining the **balloon** from further expansion.

Claims Text - CLTX (45):
inserting the catheter within the sheath so that the **mesh** portion is aligned
with the **balloon**.